Chocolate Manufacturers Association

April 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Registration of Food Facilities; Docket No. 02N-0276

The Chocolate Manufacturers Association (CMA), the National Confectioners Association (NCA), and the Cocoa Merchants' Association of America (CMAA) appreciate this opportunity to submit comments regarding the Food and Drug Administration's (FDA) proposed rule on food facility registration. 68 Fed. Reg. 5,378 (Feb. 3, 2003).

CMA is the not-for-profit trade association representing the majority of chocolate manufacturers in the United States. In addition to supplying the trade with bulk chocolate products, CMA members also manufacture a wide variety of finished chocolate and chocolate-containing confectionery products for the consumer market. NCA is the not-for-profit trade association representing more than 650 confectionery manufacturers and suppliers in the United States. CMAA is a not-for-profit organization founded in 1924 that counts as its members all major importing dealers of cocoa beans and cocoa products, the total import value of which was $1.20 billion in 2002.

While we strongly support the purposes of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the proposed regulations implementing the Bioterrorism Act, the chocolate, confectionery, and cocoa industries have many questions and concerns about their practical implementation. In particular, we believe a realistic balance must be achieved between FDA's need for information and the realities of the food industry.

1. The final rule should clarify which foreign facilities are required to register.

The proposed rule contains an exemption from registration for foreign facilities where food from that facility undergoes further manufacturing/processing or packaging (of more than a *de minimis* nature) at a subsequent foreign facility. Despite this proposed exemption, there remains considerable uncertainty as to which foreign facilities will be required to register. This is especially

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the case with crops, like cocoa beans, that are grown overseas but which undergo little or no significant processing before being exported to the United States.

Cocoa beans are grown on roughly 2 million farms worldwide. In most countries, cocoa beans are grown by subsistence farmers on small family plots. After being harvested, dried, and (in some cases) fermented, cocoa beans are taken to a local village (or, in some cases, to the port) where they are blended with beans from other farms, packed into bags, weighed, and graded. Depending on how far the grower is from the port, the beans may be held at one or more warehouses en route to the port. In addition, the beans typically are fumigated with methyl bromide or phosgene prior to export.

We would like clarification from FDA as to which foreign facilities involved in the cocoa bean trade will be required to register with FDA. We believe that the registration requirement should apply only to the foreign facility that packs the beans in the bag in which they will be exported, and any subsequent foreign facility that holds the beans.[1] However, if the beans are fumigated prior to export, we believe that fumigation constitutes manufacturing/processing. In that case, only the facility that fumigates the cocoa beans, and any subsequent facility that holds the beans, should be required to register. We request that the final rule confirm this understanding.

2. The final rule should clarify what is meant by a "mobile facility" or remove this term from the definition of "facility."

The proposed rule would define "facility" to include "a mobile facility traveling to multiple locations." 68 Fed. Reg. at 5,418. We request that FDA clarify what kind of mobile facilities are subject to the registration requirement, or remove this language from the definition of "facility." Certainly, trucks, rail cars, and shipping containers should not be considered facilities, even if they are on occasion used to store food temporarily.

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[1] It is our understanding that the farms on which cocoa beans are grown are exempt from registration. Under the proposed rule, farms generally are exempt from registration. The fermenting and drying of cocoa beans on the farm are natural processes (although artificial heat sources may be used when sun drying is not possible) and part of traditional farming practices; therefore, they should not be considered "manufacturing/processing." In any event, the packing of the cocoa beans into bags at a subsequent facility would mean that the packing facility, not the farm, is required to register. As a practical matter, we also believe that requiring the 2 million cocoa bean growers worldwide to register would overwhelm FDA and would not provide the agency with useful information.

3. The definition of "food" should be modified to omit food packaging and food contact articles.

The proposed rule would define "food" as it is defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act (FDCA), which would include "substances that migrate into food from food packaging and other articles that contact food." 21 U.S.C. § 321(f). However, we believe that Congress did not intend the Bioterrorism Act to cover food packaging materials. The expansive definition found in the FDCA enables FDA to regulate a broad category of industry in its role of protecting the public health, whereas the Bioterrorism Act has a much more limited purpose. We believe that in referencing "food intended for consumption in the United States" in Section 305 of the Act, Congress intended to restrict the definition to just that—actual food intended for consumption.

Further, there is little risk that manufacturers of food contact materials and packaging would be targets of a bioterrorist attack, and thus a registry of such manufacturers would do little to assist FDA in the event of such an attack. If, in some unlikely event, it were necessary to contact the suppliers of the food contact materials, FDA would have access to full information from the actual food manufacturer.

We believe that the requirements are more burdensome than are necessary to accomplish the goal of the Bioterrorism Act, enhancing FDA's ability to respond quickly to a threatened or actual attack on the U.S. food supply. Thus, we ask that the final rule restrict the definition to the specific purpose and requirements of the Act. Alternatively, we request that the final rule contain some justification for the overly burdensome application of the registration requirement to manufacturers of non-food items.

4. The criteria for revoking a facility's registration should be limited to those relevant to the purposes of the Bioterrorism Act.

The proposed rule requests comments on the circumstances in which a facility's registration should be revoked by FDA, and the procedures that should apply to such a revocation. Revocation of a facility's registration will effectively prohibit that facility from manufacturing/processing, packing, or holding food for consumption in the United States.

Given the serious consequences of revocation, we believe that it should be reserved for extreme situations that indicate the potential for bioterrorism, intentional contamination, or other criminal activity. In all other situations, FDA has a range of other enforcement tools that the agency should employ before seeking revocation. For example, if a food product manufactured by a facility is adulterated or misbranded, FDA's first recourse should be to request a recall. If the facility refuses to recall the product, then FDA should initiate a seizure or injunction action in federal court. Revocation should only be pursued as a last resort. In addition, we believe that a facility facing

revocation should be afforded appropriate due process protections consistent with the property rights involved. Specifically, revocation should require an adjudicative hearing in accordance with the Administrative Procedure Act (5 U.S.C. § 554).

5. If a product is refused admission because it is from an unregistered foreign facility, this determination should be reviewable.

Under the proposed rule, if a foreign facility that is required to register fails to do so, food from the unregistered foreign facility may be refused admission and held at the port of entry until registration is completed. If FDA directs removal of such food to a secure storage facility, the owner, purchaser, importer, or consignee must arrange for storage of the food in an FDA-designated secure facility; must notify FDA of the location; must move the food to the secure facility under bond; and must bear the transportation and storage expenses. The proposed rule does not provide any right for parties adversely affected by a refusal of admission to challenge that determination.

We believe there must be some mechanism for review of such determinations. There is a strong presumption in the law in favor of reviewability of agency decisions, even where the governing statute does not expressly provide for such review.

It is the rare instance in which an aggrieved party may not seek judicial review of an agency action. The Administrative Procedure Act states that judicial review shall apply to agency action "except to the extent that—(1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law." 5 U.S.C. § 701(a). The courts have held that "there is virtually a presumption in favor of judicial review unless a contrary purpose is fairly discernable in the statutory scheme." *Hayes Intern. Corp. v. McLucas*, 509 F.2d. 247 (5th Cir. 1975) (*citing Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967)). The absence of express statutory language authorizing judicial review is not enough to overcome this presumption of reviewability. Agency action typically is found to be non-reviewable only if there is a showing of "clear and convincing evidence" of a legislative intent not to allow review. *Abbott Laboratories v. Gardner*, 387 U.S. 136, 140 (1967)) (*citing* H. R. Rep. No. 1980, 79th Cong., 2d Sess., 41 (1946) ("To preclude judicial review under this bill a statute, if not specific in withholding such review, must upon its face give clear and convincing evidence of an intent to withhold it. The mere failure to provide specially by statute for judicial review is certainly no evidence of intent to withhold review.")).

While the Bioterrorism Act does not expressly provide for review of agency decisions, there is no evidence in the statute or its legislative history to overcome the presumption in favor of review. Accordingly, the final rule should provide a mechanism for review, both administrative review within FDA and judicial review in court, if a product is refused admission because it is from an unregistered foreign facility.

6. **If a product is denied admission because it is from an unregistered foreign facility, FDA should provide appropriate storage facilities at the port of entry.**

We request that FDA provide climate-controlled storage facilities, where appropriate, for foods that are held at the port of entry because they have been imported from an unregistered foreign facility.

7. **FDA should ensure the security of data on the registration system.**

If any person can access a facility registration and change the registration information, the registration system will be of no use to FDA. We request that FDA design the registration system so that only authorized persons can access and change a facility's registration information.

We appreciate this opportunity to comment.

Respectfully submitted,

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